

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 41, 43, 66, 72-75, 77, 78 and 168-173 are pending in the application, with claim 41 being the independent claim. New claims 168-173 are sought to be added. Claims 42, 44-65, 67-71, 76 and 79-167 have been canceled without prejudice to or disclaimer of the subject matter therein. Claims 41, 43, 66 and 72-75 have been amended to define Applicants' invention with greater particularity, and emphasize that the claimed peptides induce a CTL response. Support for these changes and the newly added claims can be found throughout the specification, for example, *inter alia*, at page 42, lines 27-30; page 44, lines 9-25; and page 50, line 17- page 51, line 22. The specification has amended to update the status of all U.S. patent applications disclosed therein as requested by the Examiner. These changes introduce no new matter, and their entry is respectfully requested.

The Examiner has stated that claim 74 is withdrawn as being drawn to a non-elected species. Applicants respectfully assert that claim 74 should not be withdrawn because it merely presents a further limitation to the claimed peptide. Claim 74 is directed to a composition comprising the peptide of claim 41 and a liposome, and as such is not a different species of the claimed peptide. Not in acquiescence to the Notice of Non-Compliant Amendment, but solely to advance prosecution, Applicants have amended the status of claim 74, however, clarification of the status is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Provisional Double Patenting Rejections

Claims 41, 43, 53, 66, 72, 73, 75, 77 and 78 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-11 of U.S. Patent No. 6,602,510. Applicants respectfully traverse this rejection, but request that the rejection be held in abeyance until such time that the pending claims are found allowable.

Claims 41, 43, 53, 66, 72, 73, 75, 77 and 78 were rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-31 and 35-39 of copending Application No. 10/149,915.

According to § 804(I)(B) of the Manual of Patent Examining Procedure (M.P.E.P.), when provisional double patenting issues are raised in copending applications, "[i]f the 'provisional' double patenting rejections in both applications are the only rejections remaining in those applications, the examiner should then withdraw that rejection in one of the applications (e.g., the application with the earlier filing date) and permit the application to issue as a patent. The examiner should maintain the double patenting rejection in the other application as a 'provisional' double patenting rejection which will be converted into a double patenting rejection when the one application issues as a patent."

Applicants will appropriately address the double patenting rejection in the event it is converted to an actual double patenting rejection pursuant to MPEP § 804(I)(B).

Rejection under 35 U.S.C. § 103

Claims 41, 43, 53, 66, 72, 73, 75, 77 and 78 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Grey *et al.* (WO 94/20127) in view of Panicali *et al.* (U.S. Patent No. 6,001,349). Applicants respectfully disagree.

To establish a *prima facie* case of obviousness: (1) the prior art reference (or references when combined) must teach or suggest all the claim limitations; (2) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; and (3) there must be a reasonable expectation of success. MPEP § 2143.

Applicants note that pending claims 41, 43, 66, 72-75, 77, 78 and 168-173 are directed to isolated CTL-inducing peptides comprising the oligopeptide IMIGVLVGV. Grey *et al.* teaches a motif that can be used to screen for peptides which bind to HLA-A2.1, and identifies certain peptides, derived from cancer antigens, that bind HLA-A2.1. However, Grey *et al.* does not teach any peptides comprising the oligopeptide IMIGVLVGV. Therefore, Grey *et al.* does not teach or suggest every element of Applicants' claimed invention. Furthermore, the Examiner has acknowledged that "Grey *et al.* do not teach the particular CEA derived peptide recited in the claims." (Office Action, pages 4-5). The deficiencies of Grey *et al.* are not overcome by Panicali *et al.* because Panicali *et al.* does not teach any peptides of the claimed invention.

Panicali *et al.* teaches that the amino acid sequence of CEA is known.

Applicants' claimed peptides are not discussed, nor even suggested in Panicali *et al.* At best, given the large number of possible epitopes that could be identified within CEA, one skilled in the art might find it obvious to try a variety of these epitopes to identify the claimed peptides. However, this is not the standard for obviousness. *In re Geiger*, 815 F.2d 686, 688 (Fed. Cir. 1987). Accordingly, Grey *et al.*, in view of Panicali *et al.*, does not teach or suggest of the claimed invention.

Even assuming, *arguendo*, that the Examiner has established a *prima facie* case of obviousness, Applicants assert that the *prima facie* case of obviousness can be rebutted. Rebuttal evidence may consist of a showing that the claimed compound possesses unexpected properties. *In re May*, 574 F.2d 1082 (CCPA 1978). Evidence of unobvious or unexpected advantageous properties, such as superiority in a property the claimed compound shares with the prior art, can rebut *prima facie* obviousness. MPEP § 716.02; see *In re Chupp*, 816 F.2d 643, 646 (Fed. Cir. 1987).

Applicants remind the Examiner that identification of a peptide motif is only a starting point in the identification of immunogenic, cytotoxic T lymphocyte-inducing peptides. The specification at Table VIII lists approximately 380 peptides that meet the criteria of containing an HLA-A2.1 motif. The oligopeptide IMIGVLVGV was particularly identified out of those 380 peptides based on additional beneficial characteristics it possess, such as strong HLA binding properties (Table VIII), cross-reactivity with various HLA molecules, which results in greater population coverage (Table XXII), and significant immunogenicity (Tables XXII and XXIII). The specification, at page 16, lines 28-34, clearly discloses the importance of these preferred

characteristics in selecting peptides for development as vaccine candidates. In view of the improved binding properties of the claimed peptide as compared to the 380 other peptides sharing the same motif, and in view of the significantly higher CTL induction generated as compared to other peptides sharing the same motif, Applicants respectfully assert that evidence of unexpected advantageous properties is present and is sufficient to rebut a *prima facie* case of obviousness. Therefore, Applicants respectfully assert that even assuming a *prima facie* case of obviousness has been established, a *prima facie* case of obviousness can be rebutted using the evidence described above.

Accordingly, Applicants respectfully request that the rejection be reconsidered and withdrawn.

Other Matters

The Examiner has requested a new oath or declaration based on changes made in priority claims during prosecution. Applicants respectfully request that the request be held in abeyance until allowable subject matter has been determined.


Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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